REMARKS

Each independent claim (claims 1, 13, 25 and 26) has been amended to clarify what is meant by the term "high-resolution" in the phrase "high-resolution ECG data". Claim 1 has been further amended to clarify that various steps are performed by a machine (i.e., data processor) and not a human.

In the office action, claims 1-5 and 13-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sellers (US 5,228,450). The Applicants traverse this ground of rejection for the following reasons.

First, the Examiner asserts that Sellers discloses the acquisition of high-resolution ECG data. Applicants' independent claims have been amended to clarify that the least significant bit (LSB) of the ECG data corresponds to a resolution of at most about 1 microvolt. It is common knowledge amongst persons of skill in the pertinent art that a resolution of 1 μV LSB requires an analog-to-digital converter (ADC) of at least 16 bits. In contrast, Sellers discloses a system whereby acquired analog signal are converted into digital data by a 10-bit ADC 88. The person skilled in the art appreciates that the ADC needs to have a dynamic range of 80 mV to accommodate both the ECG signals and DC drift. The LSB for a 16-bit ADC is $80,000/2^{16} = 1.22$ μV, whereas the LSB for a

10-bit ADC is $80,000/2^{10}$ = 78 μV. Therefore, the Sellers system is incapable of providing the level of resolution now recited in each of Applicants' independent claims.

In addition, while Sellers discloses that the ECG data "may be processed . . . using well known algorithms for analyzing ECG data" [Sellers, col. 4, lines 52-55], Sellers neither discloses nor suggests that the results of different ECG analysis algorithms are processed to derive a predictive score. The term "predictive score" appears nowhere in Sellers. Nor do the words "prediction" or "score". In support of the assertion that Sellers discloses deriving a predictive score, the Examiner cites column 1, lines 10-25, in the Description of the Prior Art section. However, that section says nothing about processing ECG data to derive a predictive score for a particular clinical end point. It merely states that "[d]ata acquired by Holter monitoring is useful in identifying patients who are at risk of ventricular tachycardia". There is no mention of deriving a score for use in "identifying" such patients at risk.

In view of the foregoing, the Applicants respectfully submit that Sellers does not anticipate either of independent claims 1 and 13 or any claim dependent thereon. In particular, with regard to claims 2 and 14, it should be

apparent that Sellers, if it does not disclose predictive scoring, cannot disclose training a predictive model for deriving a predictive score.

In the office action, claims 6-8 and 18-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sellers in view of Thiagarajan *et al.* (US 2003/0060724). The Applicants traverse this ground of rejection for the same reasons, set forth above, why Sellers does not anticipate claims 1 and 13 and for the following additional reasons.

Applicants' claims 6-8 and 18-20 recite specific ECG analysis algorithms, whose results are to be processed to derive a predictive score as recited in claims 1 and 13. Thiagarajan discloses a monitoring apparatus and method that analyzes the intrinsic cardiac signals from a patient to detect T-wave alternans, and use the same to derive an indication of the patient's cardiac condition. Thiagarajan does not disclose performing an ECG analysis algorithm different than T-wave alternans and then combining the results of the former and latter. The extract from Thiagarajan cited by the Examiner reads as follows:

> In the last few years, several non-invasive methodologies have been suggested for predicting ventricular malignant arrhythmias. These methods include high frequency signal-averaged electrocardiography (SAECG) for late-potential

> analysis, heart rate variability and QT dispersion analysis (Gomes J et a., 1991; Day C P et al., 1990; Task Force of the ESC and the NASPE, 1996). These methods are limited in sensitivity and specificity in screening high-risk patients for ventricular arrhythmias and sudden cardiac death (SCD). Compared to these methods, T wave alternans have proved to be more reliable estimators and perform as well as invasive, electrophysiological studies in risk stratifying patients for life-threatening arrhythmias [Gold M et al., 2000].

[Thiagarajan, ¶ 0019.] This extract clearly indicates that T-wave alternans is a "more reliable estimator" than methods such as high frequency signal-averaged electrocardiography (SAECG) for late-potential analysis, heart rate variability or QT dispersion analysis. Accordingly, there is no suggestion that the results of SAECG, heart rate variability or QT dispersion analysis should be combined or fused with the results of T-wave alternans analysis to derive a predictive score.

Furthermore, Thiagarajan (like Sellers) does not disclose the acquisition of high-resolution data. Since neither Sellers nor Thiagarajan discloses the acquisition of high-resolution ECG data or the fusion of ECG analysis algorithm results, the Applicants submit that claims 6-8 and 18-20 cannot be obvious in view of those references.

Claims 9, 11, 12, 21, 23 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sellers in view

of Verrier *et al.* (US 5,921,940). The Applicants traverse this ground of rejection for the same reasons, set forth above, why Sellers does not anticipate claims 1 and 13. Also, Verrier does not disclose or suggest the acquisition of high-resolution ECG data.

Claims 10 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sellers in view of Verrier and further in view of Nearing *et al.* (US 6,169,919). The Applicants traverse this ground of rejection for the same reasons, set forth above, why claims 9 and 21 are not obvious over Sellers in view of Verrier. Also, Nearing does not disclose or suggest the acquisition of high-resolution ECG data. As seen in column 8, line 9, Nearing also uses a 10-bit ADC, which is incapable of providing "high resolution" as that term is defined in Applicants' independent claims.

Claims 10 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sellers in view of Verrier and further in view of Nearing *et al.* (US 6,169,919). The Applicants traverse this ground of rejection for the same reasons, set forth above, why claims 9 and 21 are not obvious over Sellers in view of Verrier.

Finally, claims 25 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Verrier in view of

Nearing. As demonstrated above, neither Verrier nor Nearing discloses the acquisition of high-resolution ECG data. Accordingly, the Applicants traverse this ground of rejection.

In view of the foregoing, the Applicants respectfully submit that this application is now in condition for allowance. Reconsideration of the application and allowance of claims 1-26 are hereby requested.

Respectfully submitted,

April 27, 2006
Date

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The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date set forth below.

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